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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,384	08/20/2002	Maria Laura Gennaro	07763-042001	7084

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EXAMINER
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SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

MAIL DATE	DELIVERY MODE
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07/17/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/009,384	GENNARO ET AL.	
	Examiner Rodney P. Swartz, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 09 July 2007.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-8 and 11-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-8 and 11-20 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_

**DETAILED ACTION**

1. Applicants' Response to Office Action, received 9 July 2007, is acknowledged.

Claims 1, 2, 11, 12, 15, 16, 17, 18, 19, and 20 have been amended.

2. Claims 1-8 and 11-20 are pending and under consideration.

**Rejection Withdrawn**

3. The rejection of claims 1-8 and 11-20 under 35 U.S.C. 112, second paragraph, indefiniteness for specific properties and number/identity of conservatively substituents residues, is withdrawn in light of the amendments of the claims.

**Rejection Maintained**

4. The rejection of claims 17-20 under 35 U.S.C. 112, first paragraph, scope of enablement for diagnostic methods utilizing polypeptides, is maintained for reasons of record.

Applicants argue that the present claims state that the presence of an immune response is an indication that the subject has an *M. tuberculosis* infection, but not necessarily unequivocal proof of *M. tuberculosis* infection. After obtaining an indication of *M. tuberculosis* infection by the claimed method, one or more confirmatory tests are carried out to result in a conclusive diagnosis of *M. tuberculosis* infection.

The examiner has considered applicants' argument, but does not find it persuasive because the sole method of diagnosis in the claimed invention is assay system of steps (a) and (b) and therefore any detectable immune response is determined to label a subject as "TB-positive". As stated in the original rejection explanation, the specification contains no working examples of the claimed methods of detecting *M. tuberculosis* infected hosts utilizing the listed polypeptides or any other

compositions. The specification merely contains computer generated sequences of *M. tuberculosis* DNA and predicted *M. tuberculosis* proteins.

Applicants argue that the amendment of claims 18-20, replacing "functional" segment with "the segment retains specific antigenic properties" obviates the rejections based upon "functional segments". Applicants argue that it would be entirely routine for one skilled in the art to test whether any particular polypeptide segment of interest retained specific antigenic properties which are "capable of being recognized by either antibody molecules or antigen-specific T cell receptors on activated effector T cells".

The examiner has considered applicants' argument, but does not find it persuasive. As stated in the early explanations, the specification contains insufficient guidance and no working examples to determine if any "segment" of the claimed polypeptides actually has "specific antigenic properties" necessary for the diagnosis of *M. tuberculosis* infection. Applicants argument that it would be routine to determine such specificity is merely an invitation to experiment without a reasonable expectation of success that any segment has the necessary specific antigenic properties for the claimed diagnosis of *M. tuberculosis* infection.

### **New Rejection Necessitated by Amendment**

#### **Claim Rejections - 35 USC § 112**

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Newly amended claims 1-8 and 11-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Newly amended claims 1-8 and 11-20 are drawn to DNA sequences encoding polypeptides, and polypeptide sequences which are designated by name only. Because the sequences are not claimed by any SEQ ID Number, only a nonspecific laboratory designation, the identity of any possible DNA sequences or polypeptide sequences to be included or excluded in the claims is unclear. It is recommended that the claimed sequences be identified by sequence identifiers, i.e., SEQ ID NO:.

### **Conclusion**

7. No claims are allowed.
8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 7:30 PM EST.

Art Unit: 1645

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Jeffrey Siew, can be reached on (571)272-0787.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Rodney P. Swartz*  
RODNEY P. SWARTZ, PH.D  
PRIMARY EXAMINER  
Art Unit 1645

July 11, 2007